1.3
PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Aritadine Ointment 5% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

NAME OF INGREDIENT (S)	Pharmacopoeial Reference	Quantity (% w/w)	Label Claim
ACTIVE			
Povidone Iodine* (Assay at 10%)	USP	6	5 % w/w
INACTIVE INGREDIENTS			
Polyethylene Glycol 400	USP	57.82	
Polyethylene Glycol 3350	USP	26.00	
Sodium Bicarbonate	BP	0.18	
Purified Water q.s.to	BP	10.00	

*Contains 20% overages to compensate the losses during storage at shelf life.

3. PHARMACEUTICAL FORM

Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the prevention of infection in burns, cuts, abrasions, poison ivy rash and insect bites. The treatment of skin infections, including infections of varicose and decubitus ulcers.

4.2 Posology and method of administration

Route of administration: Topical

The affected area is cleaned; the ointment is applied as prescribed. A dressing may be applied if required.

4.3 Contraindications

Not applicable

4.4 Special warnings and precautions for use

This ointment is only to be applied topically to the skin.
Use of this preparation may interfere with tests of thyroid function. Iodine is absorbed through burns and broken skin and to a lesser extent through intact skin and may lead to toxic levels of iodine in the blood, particularly in patients with renal insufficiency. If symptoms occur suggesting changes in thyroid function, these should be investigated. In patients with impaired renal function, blood levels of iodine should be monitored. If local irritation and hypersensitivity develop, then discontinue treatment.

4.5 Interaction with other medicinal products and other forms of interaction

Use with concurrent lithium therapy has been shown to exhibit additive hypothyroidic effects. Absorption of iodine from povidone iodine through either intact skin or broken skin may interfere with thyroid function tests. Contamination with povidone iodine of several types of tests for the detection of occult blood in faeces or blood in urine may produce false-positive results

4.6 Pregnancy and lactation

During pregnancy and lactation, Povidone Iodine should only be used if strictly indicated and its use should be kept to the absolute minimum. Because of the ability of Iodine to pass through the placenta and be secreted in breast milk, and because of the increased sensitivity of the fetus and new born to Iodine, no large amounts of Povidone Iodine should be administered during pregnancy and lactation. Povidone Iodine use may induce transient hypothyroidism with elevation of TSH in the fetus or in the new born. A check of the child's thyroid function may be necessary. Any possible oral ingestion of the solution by the infant must be absolutely avoided.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Rarely. Hypersensitive skin reactions may occur (e.g., delayed contact -allergic reactions, which can appear in the form of pruritus, erythema, small blisters or similar manifestations).

In single cases acute, generalized, allergic reactions, with drop in blood pressure and/or dyspnea (anaphylactic reactions) have been reported.

The longterm use of povidone iodine ointment for the treatment of wounds and burns over extensive areas of skin can lead to a notable uptake of Iodine. In isolated cases, patients

with a history of thyroid disease can develop hyperfunction of the thyroid (iodine induced hyperthyroisdism), sometimes with symptoms such as tachycardia or restlessness.

Following uptake of large amounts of povidone iodine (e.g in the treatment of burns), the appearance of additional disorders of electrolyte imbalance and abnormal blood osmolarity, impairment of renal function with acute renal failure and metabolic acidosis have been described in the use if iodine containing products.

4.9 Overdose

Acute Iodine toxicity is manifested by abdominal symptoms, anuria, circulatory collapse, laryngeal edema resulting in asphyxia, or pulmonary edema and metabolic abnormalities.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ARITADINE Ointment is a topical microbicide active against organisms commonly encountered in skin and wound infections.

ARITADINE ointment may be used as an adjunct to systemic therapy where indicated; for primary or secondary topical infections, infected surgical incisions and other topical lesions; for degerming skin; in hyperalimentation and catheter care. The use of ARITADINE Ointment for abrasions, minor cuts, and wounds, may prevent the development of infections and permit wound healing.

Povidone Iodine is an Iodophore which is used as a disinfectant and antiseptic mainly for the treatment of contaminated wounds and pre-operative preparations of the skin and mucous membranes.

Iodophores are loose complexes of Iodine and carrier polymers. Preparations of povidone iodine gradually release Iodine to exert an effect against bacteria, fungi, virus, protozoa, cysts and spores. Povidone Iodine is thus less potent than preparations containing free iodine but is less toxic.

Povidone Iodine retains the bactericidal activity of iodine but is less potent, therefore causes less irritation to skin and mucous membranes.

5.2 Pharmacokinetic properties

Absorption: Iodine is poorly absorbed through intact skin but absorption is enhanced through denuded skin.
Distribution: Widely distributed
Metabolism: Metabolized in liver by oxidation & glucuronide conjugation, Excretion: Excreted in urine

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene Glycol 400, Polyethylene Glycol 3350, Sodium Bicarbonate.

6.2 Incompatibilities

None reported.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30^{o}C. Do not freeze. Replace the cap tightly after use.

6.5 Nature and contents of container

Aluminum Collapsible Tube of 30g

6.6 Special precautions for disposal and other handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

MERIT ORGANICS LIMITED,

PLOT N0. 2104/2/1, G.I.D.C, SARIGAM, DIST. - VALSAD, GUJARAT, INDIA.

8. MARKETING AUTHORISATION NUMBER(S)

Fresh registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Fresh registration

NAFDAC REG.NO:
KEEP OUT OF THE REACH OF CHILDREN
Manufactured by
MERIT ORGANICS LIMITED ,
PLOT N0. 2104/2/1, G.I.D.C, SARIGAM, DIST. - VALSAD, GUJARAT, INDIA.
Marketed By
MAKKI PHARMACEUTICALS LTD
55 commissioners quarters Road, Ifite Awka Anambra State Nigeria